ANSWER TO COMPLAINT – 3:08-cv-2911-CRB

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I.

PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted generally. Defendant may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Bextra®.

II.

ORIGINAL ANSWER

Response to Allegations Regarding Jurisdiction

Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and the amount in controversy, and, therefore, denies the same. However, Defendant admits that Plaintiffs claim that the parties are diverse and that the amount in controversy exceeds \$75,000, exclusive of interests and costs.

Response to Allegations Regarding the Nature of the Case

- Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies the remaining allegations in this paragraph of the Complaint.
- Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable

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defective, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining

allegations in this paragraph of the Complaint.

4. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.

- Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance 7. with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

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Response to Allegations Regarding Parties

- 8. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' age and citizenship, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 9. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 10. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies that Bextra® caused Plaintiffs injury or damages and denies the remaining allegations in this paragraph of the Complaint.
- Defendant admits that it is a Delaware corporation with its principal place of business in 11. New York. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 12. Defendant admits that it is a Delaware corporation with its principal place of business in New York. Defendant admits that it does business in New York. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 13. Defendant admits that it does business in New York. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 14. Defendant admits that it does business in New York. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 15. Defendant admits that it does business in New York. Defendant denies the remaining allegations in this paragraph of the Complaint.

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- 16. Defendant admits that it does business in the United States, including New York. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 17. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 18. Defendant admits that it is registered to do and does business in New York. Defendant is without knowledge or information sufficient to form a belief as to the judicial district in which the asserted claims allegedly arose, and, therefore, denies the same. Defendant denies any wrongful conduct, denies committing a tort in the States of New York or California, and denies the remaining allegations in this paragraph of the Complaint.

Response to Factual Allegations

- 19. Defendant admits that Bextra® was approved by the FDA, on November 16, 2001. Defendant admits, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 20. Defendant admits that Bextra® is in a class of drugs that is, at times, referred to as nonsteroidal anti-inflammatory drugs ("NSAIDs"). Defendant states that the remaining allegations in this paragraph of the Complaint are not directed toward Defendant, and, therefore, no response is required. To the extent that a response is deemed required, Defendant states that Plaintiffs fail to provide the context for the remaining allegations in this paragraph of the Complaint. Defendant is therefore without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, denies the same.
- 21. Defendant states that, as stated in the FDA-approved labeling for Bextra®, "[t]he mechanism of action is believed to be due to inhibition of prostaglandin synthesis primarily through inhibition of cyclooxygenase-2 (COX-2). At therapeutic plasma concentrations in humans valdecoxib does not inhibit cyclooxygenase-1 (COX-1)." Defendant states that the

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of the Complaint.

and, therefore, no response is required. To the extent that a response is deemed required,

Defendant states that Plaintiffs fail to provide the context for the remaining allegations in this

paragraph of the Complaint. Defendant is therefore without knowledge or information

sufficient to form a belief as to the truth of such allegations, and, therefore, denies the same.

- 22. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
- 23. Defendant states that the referenced media statement speaks for itself and respectfully refers the Court to the media statement for its actual language and full text. Any attempt to characterize the media statement is denied. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 24. Defendant admits that the sale of Bextra® was voluntarily suspended in the U.S. market as of April 7, 2005. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 25. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 26. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective

allegations in this paragraph of the Complaint.

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when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining

- Defendant is without knowledge or information sufficient to form a belief as to the truth 27. of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 28. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.
- 29. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable

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standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to First Cause of Action: Negligence and Negligence Per Se

- 30. Defendant incorporates by reference its responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.
- 31. Defendant admits that it had duties as are imposed by law but denies having breached such duties. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 32. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.
- 33. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint, including all subparts.
- 34. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of

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- Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 35. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.
- 36. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
- 37. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

- Defendant admits that the sale of Bextra® was voluntarily suspended in the U.S. market as of April 7, 2005. Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.
- 38. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
- 39. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
- 40. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
- 41. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
- 42. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Strict Products Liability

- 43. Defendant incorporates by reference its responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.
- 44. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 45. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states

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that, in the ordinary case, Bextra® was expected to reach users and consumers without substantial change from the time of sale. Defendant denies the remaining allegations in this paragraph of the Complaint.

- 46. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective or unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.
- 47 Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.
- 48. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies any wrongful conduct, denies that Bextra® is defective or unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.
- 49. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies any wrongful conduct, denies that Bextra® is defective or unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.

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- 50. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.
- 51. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 52. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 53. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant admits that it had duties as are imposed by law but denies having breached such duties. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and denies the

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- remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.
- 55. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective or unreasonably dangerous, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.
- 57. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.

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Gordon & Rees, LLP 275 Battery Street, Suite 2000 San Francisco, CA 94111 58. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.

- 59. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance 60. with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance 61. with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.
- 62. 28 Defendant states that Bextra® was and is safe and effective when used in accordance

the Complaint.

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- 1 with its FDA-approved prescribing information. Defendant states that the potential effects of
- 2 Bextra® were and are adequately described in its FDA-approved prescribing information,
 - which was at all times adequate and comported with applicable standards of care and law.
 - Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra®
 - caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of
 - 63. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
 - 64. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
 - 65. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Third Cause of Action: Breach of Express Warranty

- 66. Defendant incorporates by reference its responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.
- 67. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant admits that it provided FDA-approved prescribing information regarding Bextra®. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 68. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 28 69. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or

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- damages, and denies the remaining allegations in this paragraph of the Complaint.
- 70. Defendant admits that it provided FDA-approved prescribing information regarding Bextra®. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 71. Defendant admits that it provided FDA-approved prescribing information regarding Bextra®. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 72. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.
- 73. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant admits that it provided FDA-approved prescribing information regarding Bextra®. Defendant denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance 74 with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 75. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
- 76. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
- 77. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or

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damages, and denies the remaining allegations in this paragraph of the Complaint.

Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Fourth Cause of Action: Breach of Implied Warranties

- 79. Defendant incorporates by reference its responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.
- 80. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.
- Defendant is without knowledge or information sufficient to form a belief as to the truth 81. of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant admits that it provided FDA-approved prescribing information regarding Bextra®. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 82. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant admits that it provided FDA-approved prescribing information regarding Bextra®. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 83. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information,

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Gordon & Rees, LLP 275 Battery Street, Suite 2000 San Francisco, CA 94111 15 16 17 which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective or unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.

- 84. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant admits that it provided FDA-approved prescribing information regarding Bextra®. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 85 Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant admits that it provided FDA-approved prescribing information regarding Bextra®. Defendant denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance 86. with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant states that, in the ordinary case, Bextra® was expected to reach users and consumers without substantial change from the time of sale. Defendant denies any wrongful conduct, denies that Bextra® is defective or unreasonably dangerous, and denies remaining allegations in

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- Gordon & Rees, LLP 275 Battery Street, Suite 2000 San Francisco, CA 94111

- this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of
- Bextra® were and are adequately described in its FDA-approved prescribing information,
- which was at all times adequate and comported with applicable standards of care and law.
- Defendant denies any wrongful conduct and denies remaining allegations in this paragraph of the Complaint.
- 88. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
- 89. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
- 90. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
- 91. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Fifth Cause of Action: Fraudulent Misrepresentation

- 92. Defendant incorporates by reference its responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.
- Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information,
- 22 which was at all times adequate and comported with applicable standards of care and law.
- 23 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
- 24 of the Complaint.
- 25 94. Defendant states that Bextra® was and is safe and effective when used in accordance
- 26 with its FDA-approved prescribing information. Defendant states that the potential effects of
- 27 Bextra® were and are adequately described in its FDA-approved prescribing information,
- 28 which was at all times adequate and comported with applicable standards of care and law.

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Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

- 95. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 96. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 97. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
- 98. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information,

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Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the

which was at all times adequate and comported with applicable standards of care and law.

- remaining allegations in this paragraph of the Complaint.
- 99. Defendant states that Bextra® was and is safe and effective when used in accordance
- 5 with its FDA-approved prescribing information. Defendant states that the potential effects of
 - Bextra® were and are adequately described in its FDA-approved prescribing information,
- 7 which was at all times adequate and comported with applicable standards of care and law.
- Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph 8
 - of the Complaint.
 - 100. Defendant admits that, during certain periods of time, it marketed and co-promoted
 - Bextra® in the United States to be prescribed by healthcare providers who are by law
 - authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies
 - any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the
 - remaining allegations in this paragraph of the Complaint.
 - Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or
 - damages, and denies the remaining allegations in this paragraph of the Complaint.
 - Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or
 - damages, and denies the remaining allegations in this paragraph of the Complaint.
- 19 103. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or
- 20 damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Sixth Cause of Action: Fraudulent Concealment

- 22 Defendant incorporates by reference its responses to each paragraph of Plaintiffs' 104.
- 23 Complaint as if fully set forth herein.
- 24 Defendant states that Bextra® was and is safe and effective when used in accordance
- 25 with its FDA-approved prescribing information. Defendant states that the potential effects of
- 26 Bextra® were and are adequately described in its FDA-approved prescribing information,
- 27 which was at all times adequate and comported with applicable standards of care and law.
- 28 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph

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of the Complaint.

Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

Defendant states that Bextra® was and is safe and effective when used in accordance 107. with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint, including all subparts.

108. Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant admits that it had duties as are imposed by law but denies having breached such duties. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is

Defendant is without knowledge or information sufficient to form a belief as to the truth

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1 defective, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining 2 allegations in this paragraph of the Complaint.

- Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 113. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
- Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

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115. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Seventh Cause of Action: Negligent Misrepresentation

- 116. Defendant incorporates by reference its responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.
- Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant admits that it had duties as are imposed by law but denies having breached such duties. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance 118. with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance 120. with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information,

of the Complaint.

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Defendant states that Bextra® was and is safe and effective when used in accordance

which was at all times adequate and comported with applicable standards of care and law.

Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph

with its FDA-approved prescribing information. Defendant states that the potential effects of

Bextra® were and are adequately described in its FDA-approved prescribing information,

which was at all times adequate and comported with applicable standards of care and law.

Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and

denies the remaining allegations in this paragraph of the Complaint.

122. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

123. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

124. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Eighth Cause of Action: Fraud and Deceit

Defendant incorporates by reference its responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

126. Defendant states that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendant therefore lacks knowledge or information sufficient to form a belief as to the truth of such allegations and, therefore, denies the same.

127. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of

Bextra® were and are adequately described in its FDA-approved prescribing information,

which was at all times adequate and comported with applicable standards of care and law.

Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

Defendant denies any wrongful conduct and denies the remaining allegations in this

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paragraph of the Complaint.

- Defendant states that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant admits that it had duties as are imposed by law but denies having breached such duties. Defendant denies the remaining allegations in this paragraph of the Complaint.
- 130. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

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with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph

Defendant states that Bextra® was and is safe and effective when used in accordance

of the Complaint.

Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

- 136. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 138. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

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- Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 139. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- 142 Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of

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Bextra® were and are adequately described in its FDA-approved prescribing information
which was at all times adequate and comported with applicable standards of care and law
Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
of the Complaint.

- Defendant states that Bextra® was and is safe and effective when used in accordance 144. with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance 145. with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.
- Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.
- Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

of the Complaint.

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Gordon & Rees, LLP 275 Battery Street, Suite 2000 San Francisco, CA 94111 16 with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

Defendant states that Bextra® was and is safe and effective when used in accordance

Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph

Defendant is without knowledge or information sufficient to form a belief as to the truth

of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,

and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective

when used in accordance with its FDA-approved prescribing information. Defendant states that

the potential effects of Bextra® were and are adequately described in its FDA-approved

prescribing information, which was at all times adequate and comported with applicable

standards of care and law. Defendant denies any wrongful conduct and denies the remaining

allegations in this paragraph of the Complaint.

Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or

damages, and denies the remaining allegations in this paragraph of the Complaint.

153. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or

damages, and denies the remaining allegations in this paragraph of the Complaint.

21 154. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or

damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Ninth Cause of Action: Loss of Consortium

155. Defendant incorporates by reference its responses to each paragraph of Plaintiffs'

Complaint as if fully set forth herein.

Defendant is without knowledge or information sufficient to form a belief as to the truth 156.

27 of the allegation in this paragraph of the Complaint regarding Plaintiffs' marital status, and,

28 therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the $_{2} \parallel_{157}$

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Complaint.

- 157. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.
- 158. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to Prayer for Relief

Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiffs injury or damages, and denies the remaining allegations in Plaintiffs' Prayer for Relief, including all subparts.

III.

GENERAL DENIAL

Defendant denies the allegations and/or legal conclusions set forth in Plaintiffs' Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendant reserves the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendant affirmatively shows that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendant's labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendant, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

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Third Defense

3. At all relevant times, Defendant provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendant's warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendant.

Sixth Defense

6. Plaintiffs' action is barred by the statute of repose.

Seventh Defense

7. Plaintiffs' claims against Defendant are barred to the extent Plaintiffs were contributorily negligent, actively negligent or otherwise failed to mitigate Plaintiffs' damages, and any recovery by Plaintiffs should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendant and for whose acts or omissions Defendant is not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendant cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiffs were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or

act of God.

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Eleventh Defense

11. Defendant affirmatively denies that it violated any duty owed to Plaintiffs.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided adequate warnings to Plaintiffs' treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

Fifteenth Defense

Plaintiffs' causes of action are barred, in whole or in part, by the lack of a defect as the 15. Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

Plaintiffs' alleged injuries/damages, if any, were the result of misuse or abnormal use 16. of the product Bextra® after the product left the control of Defendant and any liability of Defendant is therefore barred.

Seventeenth Defense 17. Plaintiffs' alleged injuries/damages were not caused by any failure to warn on the part

of Defendant.

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18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

Eighteenth Defense

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Nineteenth Defense

8 9 19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

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Twentieth Defense

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Plaintiffs are barred from recovering against Defendant because Plaintiffs' claims are 20. preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

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Twenty-first Defense

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Plaintiffs' claims are barred, in whole or in part, under the applicable state law because 21. the subject pharmaceutical product at issue were subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

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Twenty-second Defense

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22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

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Twenty-third Defense

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23. Plaintiffs' claims are barred, in whole or in part, by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

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Twenty-fourth Defense

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24. Plaintiffs' claims are barred, in whole or in part, because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable

federal laws, regulations, and rules.

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"direction or warnings" as to the use of the subject pharmaceutical product within the meaning

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of Comment i to Section 402A of the Restatement (Second) of Torts.

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Twenty-sixth Defense

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Plaintiffs' claims are barred or limited to a product liability failure to warn claim 26. because Bextra® is a prescription pharmaceutical drug and falls within the ambit of

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Restatement (Second) of Torts § 402A, Comment k.

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Twenty-seventh Defense

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Plaintiffs' claims are barred, in whole or in part, because the subject pharmaceutical 27. product at issue "provides net benefits for a class of patients" within the meaning of

Restatement (Third) of Torts: Products Liability, § 6, Comment f.

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Twenty-eighth Defense

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28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

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Twenty-ninth Defense

18 19 29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs failed to plead facts sufficient under the law to justify an award of punitive damages.

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Thirtieth Defense

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30. Defendant affirmatively avers that the imposition of punitive damages in this case

22 23 would violate Defendant's rights to procedural due process under the Fourteenth Amendment

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of the United States Constitution and the Constitutions of the States of California and

Missouri, and would additionally violate Defendant's rights to substantive due process under

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Thirty-first Defense

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31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and

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Fourteenth Amendments to the United States Constitution.

the Fourteenth Amendment of the United States Constitution.

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Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiffs' punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendant's nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendant.

Thirty-fifth Defense

35. Plaintiffs failed to provide Defendant with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendant's rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical product were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States

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Constitution, and applicable provisions of the Constitutions of the States of Kansas and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, Pacific Mutual Life Ins. Co. v. Haslip, 499 U.S. 1 (1991), TXO Production Corp. v. Alliance Resources, Inc., 509 U.S. 443 (1993); BMW of North America, Inc. v. Gore, 519 U.S. 559 (1996); and State Farm Mut. Auto Ins. Co. v. Campbell, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package inserts and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

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Forty-first Defense

41. If Plaintiffs sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendant and over whom Defendant had no control and for whom Defendant may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendant's conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiffs.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendant's conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and

Forty-eighth Defense

3 4 48. The claims must be dismissed because Plaintiffs would have taken Bextra® even if the product labeling contained the information that Plaintiffs contend should have been provided.

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Forty-ninth Defense

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49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

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Fiftieth Defense

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50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

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Fifty-first Defense

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51. Defendant's liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendant seeks an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged

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injuries and damages, if any, of Plaintiffs.

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Fifty-second Defense

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Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that 52. the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

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Fifty-third Defense

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22 53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®

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is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act

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("FDCA"), 21 U.S.C. §§ 301 et seq., and regulations promulgated there under, and Plaintiffs'

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claims conflict with the FDCA, with the regulations promulgated by FDA to implement the

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FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,

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and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra. Accordingly, Plaintiffs' claims are preempted by the

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Supremacy Clause of the United States Constitution, Art. VI, cl. 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendant states on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation as may apply.

Fifty-sixth Defense

56. Defendant states on information and belief that any injuries, losses, or damages suffered by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendant. Therefore, Plaintiffs' recovery against Defendant, if any, should be reduced pursuant to California Civil Code § 1431.2.

Fifty-seventh Defense

57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendant, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

Defendant states that to the best of Defendant's knowledge, information, and belief, 58. reasonable discovery will likely produce evidentiary support demonstrating that the fault of others for whom Defendant is not responsible directly caused or contributed to Plaintiffs' injuries, and the fault of Plaintiffs and such others should be compared pursuant to K.S.A. § 60-258(a).

Fifty-ninth Defense

59. Plaintiffs' claims are barred by Defendant's compliance with relevant legislative and San Francisco, CA 94111

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administrative regulatory safety standards authorized by the Kansas Product Liability Act, K.S.A. §§ 60-3301, et seq.

Sixtieth Defense

60. To the extent Plaintiffs contend that Plaintiffs are entitled to damages pursuant to a personal injury claim, which contention is expressly denied, claims for non-economic losses may not exceed \$250,000 pursuant to K.S.A. § 60-19a.

Sixty-first Defense

61. Plaintiffs' claims against Defendant are barred by K.S.A. § 60-3306.

Sixty-second Defense

62. Plaintiffs' claims against Defendant are limited by K.S.A. § 60-1903.

Sixty-third Defense

63. Defendant states that any award of punitive damages in this case would violate Defendant's procedural and substantive due process rights because there are insufficient circumstances in this case to support the reasonableness of an award of punitive damages and there are inadequate legal and procedural constraints imposed on the fact finder's discretion to impose such awards. The standard for punitive damages in Kansas lack sufficient objective criteria and procedural safeguards to give a jury adequate criteria or an appropriate range of proportionality regarding punitive damages.

Sixty-fourth Defense

64. Defendant states that it would violate Defendant's rights guaranteed by the United States Constitution and the Kansas Constitution to impose punitive damages against it which are penal in nature by requiring a burden of proof on Plaintiffs which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases. In the alternative, entitlement to such damages would be provided by a "clear" and "convincing" standard of proof, in view of insufficient substantive and procedural protections under Kansas law regarding punitive damages.

Sixty-fifth Defense

65. Defendant reserves the right to supplement its assertion of defenses as it continues with

	9	ase 3.06-cv-02911-CRB Document 3 Filed 07/16/2006 Page 42 01 44						
	1	its factual investigation of Plaintiffs' claims.						
	2	IV.						
	3	<u>PRAYER</u>						
	4	WHEREFORE, Defendant prays for judgment as follows:						
	5	1. That Plaintiffs take nothing from Defendant by reason of the Complaint;						
	6	2. That the Complaint be dismissed;						
	7	3. That Defendant be awarded its costs for this lawsuit;						
	8	4. That the trier of fact determine what percentage of the combined fault or other liability						
	9	of all persons whose fault or other liability proximately caused Plaintiffs' alleged						
	10	injuries, losses or damages is attributable to each person;						
	11	5. That any judgment for damages against Defendant in favor of Plaintiffs be no greater						
2000 111	12	than an amount which equals their proportionate share, if any, of the total fault or other						
Gordon & Rees, LLP Battery Street, Suite 2000 n Francisco, CA 94111	13	liability which proximately caused Plaintiffs' damages; and						
Gordon & Rees, 275 Battery Street, S San Francisco, CA	14	6. That Defendant has such other and further relief as the Court deems appropriate.						
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	7	July 16, 2008		TUCKER ELLIS & WEST LLP	
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ANSWER TO COMPLAINT – 3:08-cv-2911-CRB